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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,242	04/13/2004	Daniella I. Zheleva	CCI-014CP2	9212

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EXAMINER	
CHISM, BILLY D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,242	ZHELEVA ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-73* is/are pending in the application.

4a) Of the above claim(s) *57-59,63,64,67 and 68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-56,60-62,65,66 and 69-73* is/are rejected.

7)☒ Claim(s) *50 and 71-73* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/09/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of the species corresponding to SEQ ID NO: 295 in the reply filed on November 09, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. The elected species SEQ ID NO: 295 was found free of the art and allowable. The search was extended to other members of the genus for which prior art was found. Those claims that do not read on the anticipated species are withdrawn from consideration; claims 57-59, 63-64 and 67-68 are withdrawn.

Claim Objections

3. Claims 50 and 71-73 is objected to because of the following informalities: claim 50 fails to recite "formula V"; claims 71-73 are objected to for the recitation of amino acid sequences that do not fit the elected subject matter or the species to which art is presently applied (see for example SEQ ID NOs: 296, 298-299, 301-320, 322-323, 325-326, 328-347, 349-350, 352-353, 355-376). Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 50-56, 60-62, 65-66, and 69-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The claims 49-51 are rejected because it is unclear as to whether the claims are open or closed language regarding whether the formula V is limited to consisting of the penta-peptide or is merely comprising the penta-peptide.

7. The claims 50-56, 60-62, 65-66, 69-70 are indefinite for the recitation of limitations on specific amino acid residues that are not defined in the base claims. Claims 50 and 51, for example, lack definitions to the X residues in the claimed formula; thus, all subsequently dependent claims are adding limitations on undefined amino acid residues and themselves are indefinite limitations.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 49-56, 60-62, 65-66, 69-71 rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/42222 ('2222). The search was extended to another species which was disclosed in "2222. '2222 teaches the species RRLIF (page 63, lines 16-19). This species meets the and anticipates the limitations of the instant claims 49-56, 60-62, 65-66, 69-71, additionally, '2222 teaches many variants, i.e. page 75 line 20, of the instantly claimed formulas as applied by the variant definitions in the instant specification.

10. Claims 49-56, 60-62, 65-66, 69-71 rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,962,792 B1 ('792). The '792 patent teaches RRLIF (SEQ ID NO: 12), which meets the limitations of the instant claims 49-56, 60-62, 65-66, 69-71. Additionally, the '792 patent teaches variants of the RRLIF penta-peptide as they are described in the instant specification, wherein the variants of peptide formula V are "modified by at least one of a deletion, addition or substitution of one or more amino acid residues", at pate 32, lines 25-31.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 49-56, 60-62, 65-66, 71-73 are rejected under 35 U.S.C. 103(a) as being obvious over '2222, (cited above). At page 5, lines 17-21 and at pages 79-80, '2222 teaches the formula xyLzF, wherein x is Arginine and y and z are any amino acid. This formula and the limitations on the open residues renders obvious many variants and sequences of the instantly claimed formula V sequence of claims 49-56, 60-62, 65-66, 71-73, i.e. SEQ ID NOs: 294, 297, 300, 321, 324, 327, 348, 351, 354 and 377 of claims 71-73.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 49-56, 60-62, 65-66 and 70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-22, 24-25, 58-64, 66, 70-78 and 80-83 of copending Application No. 09/726,470 ('470). The '470 claims are drawn to many peptide sequences that comprise the instantly claimed peptide formula V of instant claims 49-56, 60-62, 65-66, and 70, i.e. the '470 claimed sequences comprise the sequence --RX_4LX_5F--. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to various sequence possibilities and variants of peptide formula V. Due to the indefiniteness of the instant claims regarding whether the claim language is opened or closed, the instant claims are interpreted as being open language for purposes of this rejection. Therefore, the '470 claims render obvious the instant claims wherein all the

required limitations are claimed. In the case that the language is to be closed by amendment, it should be noted that the claims would still render obvious variants of the instantly claimed peptide formula V.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

15. No claims are allowed. The elected species of SEQ ID NO: 295 is free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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B. DELL CHISM
PATENT EXAMINER